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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,706	07/28/2006	Martin Muller	14836-56083	2550

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EXAMINER

SAUCIER, SANDRA E

ART UNIT	PAPER NUMBER
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1651

NOTIFICATION DATE	DELIVERY MODE
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11/10/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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jxs@mmmlaw.com
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Office Action Summary

Application No.

10/587,706

Applicant(s)

MULLER ET AL.

Examiner

Sandra Saucier

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 22 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1–23 are pending. Claims 1–21 are considered on the merits. Claims 22, 23 are withdrawn from consideration as being drawn to a non-elected invention. The claims are examined to the extent of the elected species of the substrate, limonene and the product carvone.

Applicants argue that the examiner has examined claim 22 which is directed to a different species than the elected species, and that 22 and 23 do not appear to be withdrawn because the examiner rejected claim 22 under indefiniteness.

First, the examiner regrets the clerical error made in the rejection of claim 22 under 35 USC 112, second. Please note that both the beginning paragraph of the office action and the cover sheet clearly indicate that 22 is withdrawn. Examination for prior art has clearly not been extended to another species, thus this the argument is disingenuous. Second, the election of species requirement has been made final in the previous office action and will not be revisited by the examiner until the claims to the instantly examined species have been found to be allowable.

Claim Rejections – 35 USC § 112

INDEFINITE

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is indefinite because it does not define what the variable M is. Please cancel.

Applicant is thanked for the extensive revisions to the claims which have put them in better condition for examination.

Claim Rejections – 35 USC § 103

Claims 1–19, 21 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Onken *et al.* [4] in view of Sundari *et al.* [2] or the ATCC Catalog [U] and Taubert *et al.* [5].

The claims are interpreted to be directed to a process comprising: obtaining a lyophilized mycelium of ascomycetes, basidiomycetes or deuteromycetes rehydrating the lyophilized mycelium, contacting the rehydrated mycelium with a terpene hydrocarbon substrate (limonene) thereby converting the substrate to a flavor-active terpene (carveone or carvone).

The references are relied upon as explained below.

Onken *et al.* disclose the use of the substrate adapted basidiomycete, *Pleurotus sapidus*, in a submerged culture to transform the substrate R (+) limonene to carvone. The culture has been homogenized with an ultraturrax homogenizer. The transformation is carried out in a two phase system without the addition of solvents. The disclosure lacks the use of lyophilized basidiomycetes in the bioconversion.

Sundari *et al.* teach the lyophilization of mycelium of basidiomycete fungi including species of *Pleurotus*.

ATCC routinely lyophilizes fungi species of *Fusarium*.

Taubert *et al.* teach different disintegration method for filamentous fungi, Fig 1.

The substitution of rehydrated mycelium for the fresh mycelium of the prior reference would have been obvious because vegetative mycelium has been lyophilized as taught by ATCC Catalog or Sundari *et al.* Also, once the mycelium is rehydrated, it is indistinguishable from fresh mycelium. Therefore, if one of skill in the art wishes to freeze-dry and then rehydrate mycelium prior to use in a biotransformation method, this is well within the purview of one of

ordinary skill in the art. Also, since the example does not incorporate the use of a sonicating step, merely stating that the rehydrated mycelium “was reduced to small pieces”, the use of an Ultra-Turrax homogenizer is considered to be the equivalent of sonication/extrusion because use of an Ultra-Turrex homogenizer is also a disintegration method which reduces mycelium into small pieces according to Taubert *et al.*, Fig. 1.

Claim 20 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Onken *et al.* [4] in view of Sundari *et al.* [2] or the ATCC Catalog [U] as applied to claims 1–19, 21 above, and further in view of Kaspera *et al.* [V].

The claim is further directed to the use of a *Fusarium* species to convert (R)-(+)–limonene to cis-(+)-carveol.

Kaspera *et al.* teach that *Fusarium proliferatum* converts (R)–limonene to cis-(+)-carveol. The reference also teaches that *Pleurotus sapidus* converts either S or R limonene to R-(+) and S-(-)-carvone.

The substitution of a species of *Fusarium* for the species of *Pleurotus* in the method of Onken *et al.* would have been obvious because it is known that a species of *Fusarium* converts (R)-(+)–limonene to cis-(+)-carveol.

One of ordinary skill in the art would have been motivated at the time of invention to make these substitutions in order to obtain the resulting compound as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

All elements are taught in the prior art. No claim is allowed.

Response to Arguments

Applicant's arguments filed 9/21/09 have been fully considered but they are not persuasive.

Applicants argue that lyophilization and rehydration of the mycelium gives better performance than the methods disclosed in the prior art. While this may be true, there is no objective evidence of superior yields in the application. Applicant argues that Onken et al. precultivates for 2.5 days. First, it is uncertain how long and in what media the step termed "rehydration" is performed. Rehydration may be interpreted to be a precultivation prior to the introduction of substrate. Second, one of skill in the art may continue a reaction of biotransformation for as long as wished. It is the combination of the time period and the yield that demonstrate unexpected results. Without such as showing or other objective evidence, the rehydration of a lyophilized mycelium, which period of time is without limit and may encompass a 2.5 day precultivation, is considered to be within the purview of one of skill in the art.

This argument is merely the argument of counsel and is unsupported by evidence or declarations of those skilled in the art. Counsel's arguments cannot take the place of objective evidence. *In re Schulze*, 145 USPQ 716 (CCPA 1965); *In re Cole*, 140 USPQ 230 (CCPA 1964); and especially *In re Langer*, 183 USPQ 288 (CCPA 1974).

Conclusion

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In

no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). It is applicants' burden to indicate how amendments are supported by the ORIGINAL disclosure. Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Sandra Saucier/
Primary Examiner
Art Unit 1651